K100662

# 510(k) Summary for the FemVue™ Cornual Balloon Catheter

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| **Date of Summary:** | April 7, 2010 |

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| **510(k) Submitter and Primary Contact:** | Lisa Peacock<br>Vice President, Regulatory Affairs<br>Femasys Inc.<br>5000 Research Court<br>Suite 100<br>Suwanee, GA 30024<br>Tel: 770-500-3910<br>Fax: 770-500-3980<br>lpeacock@femasys.com |
| **Device Common Name:** | Hysterosalpingography or Hysterosonography Catheter |
| **FDA Device Classification Name:** | Uterine Manipulator/Injector Cannula |
| **Product Code:** | LKF |
| **Classification Regulation:** | Unassigned |
| **Device Class:** | Unclassified, Pre-Amendment 510(k) Submission |
| **Panel:** | Obstetrics/Gynecology |
| **Indication for Use:** | Intended for the delivery of contrast media during hysterosalpingography (HSG) and saline infusion hysterosonography (SIS) for the evaluation of the fallopian tube(s) selectively and/or the uterus. The following are some clinical indications: suspected polyps, fibroids, adhesions, or endometrial thickening, and/or the selective evaluation of fallopian tube patency. |
| **Device Description:** | The FemVue Cornual Balloon Catheter ("FCBC") is a latex-free Balloon Catheter within a transcervical Delivery Sheath. |
| **Predicate Device:** | FemVue™ Catheter System, K083690 |

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**Summary of Testing:**

The FCBC was tested by the following non-clinical methods to demonstrate that the device is substantially equivalent to the predicate device in functionality, safety, and effectiveness:

- The cytotoxicity, irritation, sensitization and acute systemic toxicity biocompatibility methods of ISO 10993
- Tensile testing of joint bonds
- Component functionality
- Inflation balloon integrity testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Ms. Lisa Peacock
Vice President Regulatory Affairs
Femasys Inc.
5000 Research Court, Suite 100
SUWANEE GA 30024

APR - 7 2010

Re: K100662
Trade Name: FemVue™ Cornual Balloon Catheter
Regulation Number: N/A
Regulation Name: Uterine Manipulator/Injector Cannula
Regulatory Class: Unclassified
Product Code: LKF
Dated: March 5, 2010
Received: March 8, 2010

Dear Ms. Peacock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K100662

Device Name: FemVue™ Cornual Balloon Catheter

Indications for Use:

The FemVue™ Cornual Balloon Catheter is intended for the delivery of contrast media during hysterosalpingogram (HSG) and saline infusion hysterosonography (SIS) for the evaluation of the fallopian tube(s) selectively and/or the uterus. The following are some clinical indications: suspected polyps, fibroids, adhesions, or endometrial thickening, and/or the selective evaluation of fallopian tube patency.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K100662